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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,112	03/05/2007	Craig A. Judy	3488/105	1150

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EXAMINER	
PURDY, KYLE A	
ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,112	JUDY ET AL.	
	Examiner	Art Unit	
	Kyle Purdy	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 12-27* is/are pending in the application.

4a) Of the above claim(s) *15-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 12-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The Examiner acknowledges receipt of the amendments filed on 09/11/2009 wherein claim 1 has been amended and claims 10 and 11 have been cancelled.

2. Claims 1-9 and 12-14 are presented for examination on the merits. The following rejections are made.

Response to Applicants' Arguments

3. Applicants arguments filed 09/11/2009 regarding the rejection of claims 1-14 made by the Examiner under 35 USC 103(a) over Dandiker et al. (US 5425950) in view of Holt et al. (US 6740341) have been fully considered and they are found persuasive. It's noted that claims 9 and 10 have been overcome by cancellation of the claims.

New Rejections
Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. **Claims 1, 2, 4 and 12-14 rejected under 35 U.S.C. 102(e) as being anticipated by Guo et al. (US 2004/0068000; filed 10/02/2002), evidenced by Luber et al. (US 2003/0068373).**

6. Guo is directed to compression coated tablets. Guo discloses a tablet having a core and a mantle. The core and mantle are the following:

Compression Coated Tablet	
Tablet cores	
(1) Sumatriptan succinate*	70 mg
(2) Lactose	58 mg
(3) Microcrystalline cellulose	16 mg
(4) Croscarmellose Sodium	4.5 mg
(5) Magnesium stearate	1.5 mg
(6) Purified water	Qs
Total	150 mg
Equivalent to 50 mg free base.	
Compression coating layer	
(1) Lactose	127.5 mg
(2) Microcrystalline cellulose	120.0 mg
(3) Magnesium Stearate	2.5 mg
Total	250 mg
	(per tablet)

From the above, sumatriptan is present at a weight percent of about 46%, lactose (filler) at about 38%, microcrystalline cellulose (binder) at about 10%, croscarmellose sodium (disintegrant) at about 3% and magnesium stearate at about 1%. The coating contains substantially the same materials, and does not contain sumatriptan. The coating contains lactose (filler) in an amount of about 50%, microcrystalline cellulose (disintegrant) at about 48% and magnesium stearate (lubricant) at about 1%. The weight ratio of the mantle to core is 1.6:1. It's noted that microcrystalline cellulose can function as a binder and a disintegrant. See Luber et al., [0018].

7. With respect to the dissolution rates of the core and mantle, they are not specifically disclosed by Guo. However, as the formulation is identical in all respects, they would necessarily possess the properties which Applicants claims their own invention has. As of now, the claimed product and the product of the art are identical in that they both core and mantle, both comprising substantially the same materials. Where the claimed and prior art products are

identical or substantially identical in composition, said composition must have the same properties, unless shown otherwise. See MPEP 2112.01.

8. Thus, Guo anticipates the instantly rejected claims.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. **Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Guo et al. (US 2004/0068000; filed 10/02/2002), evidenced by Luber et al. (US 2003/0068373).**

13. Guo is relied upon for disclosure described in the rejection of claims 1, 2 4 and 12-14 under 35 U.S.C. 102(e).

14. Guo teaches that the total compression coating comprises an amount from 20-95% based on weight, preferably from 50-70% based on weight.

15. Guo fails to specifically teach a mantle:core weight ratio as being less than or equal to 1.5:1.

16. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Guo with a reasonable expectation for success in arriving at a tablet formulation comprising a core:mantle weight ratio equal to or less than 1.5:1. In Guo's examples, the weigh ratio of the mantle with respect to the entire dosage is about 70%. However, it would have been within the purview to any ordinary skilled artesian to reduce the weight percentage of the coating, thereby reducing the weight ratio to below 1.5:1. For instance, a weight ratio of 20% would be equivalent to a mantle:core weight ratio of 1:5 (or 0.2:1). Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

17. **Claims 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guo et al. (US 2004/0068000; filed 10/02/2002) in view of Shirai et al. (US 5082669; published 01/21/1992), evidenced by Luber et al. (US 2003/0068373).**

18. Guo is relied upon for disclosure described in the rejections of claims 1, 2,4 and 12-14 under 35 U.S.C. 102(e) and claim 3 under 103(a).

19. Guo fails to teach a binder being present in the outer mantle.

20. Shirai is directed to rapid release oral composition with taste masking benefit. It's taught that the outer coating is to comprise a hydropropylmetylcellulose (HPMC; a binder) in an amount of about 20% of the total coating weight (see Examples 1-5). The binder is taught to provide a film layer which improves the taste masking of the core material, but does not impair the immediate release of the coated material.

21. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Guo and Shirai with a reasonable expectation for arriving at a rapid release tablet formulation wherein the outer coating comprises a binder such as polyvinylpyrrolidone. One would have been motivated to provide a binder to the outer mantle because it would aid in providing a more cohesive film layer around the core material thereby improving the taste masking benefit of coating. One would have been motivated to provide the HPMC or any other equivalent binder in such an amount with a reasonable expectation for success in successful taste masking of the interior material while not compromising the rate of release of the core material. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

Conclusion

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

23. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

24. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kyle Purdy/
Examiner, Art Unit 1611
January 27, 2010

/David J Blanchard/
Primary Examiner, Art Unit 1643